K073331 (pg. 1 of 2)

DVO
Extremity Solutions
720 E. Winona Ave., Warsaw, IN 46580

FEB 19 2008

510(k) Summary of Safety and Effectiveness

SUMMARY PREPARED: November 26, 2007

510(k) SPONSOR and APPLICANT:
DVO™ Extremity Solutions, LLC
720 E. Winona Ave., Warsaw IN 46580

CONTACT PERSON:
Jeff Ondrla,
Vice President, Product Development
(574) 527-9951
JOndrla@Tornier.com

TRADE NAME: Extended Articulation Humeral Heads

COMMON NAMES: Shoulder prosthesis, humeral head

CLASSIFICATION, CLASS and PRODUCT CODE: 21 CFR 888.3690, Class II, 87 HSD

PREDICATE DEVICES:
DePuy Global Advantage Extended Humeral Heads, K000575
DVO Total and Hemi Shoulder System, K060988

DEVICE DESCRIPTION:
The Extended Articulation Humeral Heads are an addition to the previously cleared modular DVO Total and Hemi Shoulder System. The cobalt chrome alloy, semi-spherical heads mate with the previously cleared humeral stems through a locking taper. The heads are highly polished. They do not articulate with the previously cleared glenoids as they are intended to be used in hemi-arthroplasty applications only.

The heads are available in four sizes, 44 to 56mm, in 4mm increments, and in heights of 18 and 21 mm.

(Continued on next page)

DVO
Extremity Solutions
720 E. Winona Ave., Warsaw, IN 46580

510(k) Summary of Safety and Effectiveness

INTENDED USE:

The DVO™ Total Extended Articulation Humeral Heads are intended for use in hemi-shoulder arthroplasty.

INDICATIONS FOR USE:

The DVO™ Total Extended Articulation Humeral Heads, for use in hemi-shoulder replacement, are indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Rotator cuff tear arthropathy.

Humeral stems and glenoids labeled "for cemented use only" are indicated only for use with bone cement. Humeral stems are also indicated for press-fit uncemented use or for use with bone cement. These are sterile, single use devices.

COMPARISON TO PREDICATES:

The DVO Extended Articulation Humeral Heads are similar to the listed predicate devices in intended use for hemi shoulder replacement, indications for use, design, materials of construction (cobalt chrome alloy), methods of sterilization (gamma irradiation), packaging, and manufacturing methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2008

DVO™ Extremity Solutions, LLC
% Mr. Jeff Ondrla
Vice President, Product Development
720 East Winona Avenue
Warsaw, Indiana 46580

Re: K073331
Trade/Device Name: DVO™ Extended Articulation Humeral Heads
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: November 26, 2007
Received: December 11, 2007

Dear Mr. Ondrla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073331

Device Name: DVO™ Extended Articulation Humeral Heads

Indications for Use: The DVO™ Extended Articulation Humeral Heads for use in hemi-shoulder replacement are indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Rotator cuff tear arthropathy.

Humeral stems and glenoids labeled "for cemented use only" are indicated only for use with bone cement. Humeral stems are also indicated for press-fit uncemented use or for use with bone cement. These are sterile, single use devices.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073331